

## **REMARKS**

### **Status of the Claims**

Claims 1-15 were pending as originally filed. Claims 1 and 6-15 were withdrawn from consideration pursuant to a Restriction Requirement that has been made FINAL and claims 2-5 were examined.

By amendment herein, claims 1-15 have been amended to clarify that the accessible sequences are sequences that correspond to accessible regions of cellular chromatin and are isolated based on their altered reactivity to a probe that identifies such accessible regions. See, e.g., page 12, lines 26-33 and page 29, lines 17-23. Thus, claims 1-15 are pending as shown above, and claims 2-5 are under active examination.

### **Restriction Requirement**

As noted above the Restriction Requirement as between 10 allegedly distinct groups has been made FINAL. (Office Action, paragraphs 1-5) on the grounds that U.S. Patent No. 5,474,796 (hereinafter "Brennan") discloses arrays as claimed. *Id.* In addition, it was asserted that "no evidence has been presented" showing the Brennan does not disclose the "very nucleic acids encompassed by the claims." *Id.* at paragraph 2.

In fact, the evidence of record clearly establishes that Brennan does not disclose arrays as claimed. Specifically, the claimed subject matter requires that the array be made of entirely of isolated cellular polynucleotide sequences that have been isolated based on their accessibility in cellular chromatin. As previously noted, Brennan discloses only arrays made up from synthetic oligonucleotides. Not only are Brennan's polynucleotides not isolated from cellular sequences as claimed, the Brennan's arrays are not made up solely of sequences that are accessible regions of cellular chromatin. Thus, contrary to the Examiner's assertion, Brennan, by default, does not disclose the claimed arrays. As determined by the ISA, claims 1-15 share a special technical feature (arrays of sequences of accessible regions of cellular chromatin) that is novel over Brennan. Hence, unity of invention is present and the Restriction Requirement should be withdrawn.

Applicants again expressly reserve their right to petition the Restriction Requirement if it is made FINAL. Furthermore, Applicants reserve the right to rejoinder of method claims

depending from the elected composition claims and also reserve their right under 35 USC §121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application.

### **Information Disclosure Statements**

Applicants note with appreciation return of the signed PTO/SB/08A forms indicating the references submitted with the Information Disclosure Statements received on December 12, 2005.

Applicants submit an additional IDS herewith.

### **Specification**

The specification was objected to for containing embedded hyperlinks. (Office Action, paragraph 6).

In response, Applicants have amended the specification as shown above to remove the embedded hyperlink on page 20, thereby obviating this objection.

### **35 U.S.C. § 112, 2<sup>nd</sup> paragraph**

Claims 2 to 5 were rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph as allegedly indefinite with respect to what constitutes that meets and bounds of “accessibility.” (Office Action, paragraph 9).

Applicants submit that that the term “accessible” sequence was amply clear to the skilled artisan. Nonetheless, to advance prosecution Applicants have amended the claims to make explicit what was implicit in the term “accessible sequences,” namely that they correspond to accessible regions of cellular chromatin and are isolated based on their altered reactivity to probes of chromatin structure known in the art. See, also, Ref. A34 of the IDS filed December 8, 2005 as well as references in the attached IDS. Thus, the claims are clear and definite as written and the rejection may be withdrawn.

**35 U.S.C. § 102(b)**

Claims 2 to 5 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Brennan. (Office Action, paragraphs 12 and 13). As noted with regard to the Restriction Requirement, Brennan was cited for teaching arrays of oligonucleotides that comprise all possible 10mers. *Id.* at paragraph 12. In addition, it was alleged that because the claims are product by process claims, there is no structural difference between the claimed arrays and those disclosed in Brennan. *Id.* at paragraph 13.

Applicants traverse the rejection and supporting remarks.

Anticipation is a rigorous standard – every limitation of the claim at issue must appear identically in a single reference for a rejection under 35 U.S.C. § 102 to stand. *In re Bond*, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Furthermore, in order to show inherent anticipation, the burden is on the Examiner to show that Brennan teaches an array of sequences that necessarily and inevitably correspond to accessible regions of cellular chromatin.<sup>1</sup>

In the instant case, it has not been shown that every limitation of the claims appears identically in Brennan. Specifically, claims 2-5 are drawn to arrays comprising sequences corresponding to accessible regions of cellular chromatin. Furthermore, the sequences on the array are isolated from cellular chromatin.

By contrast, Brennan relates to arrays of synthetic oligonucleotides. These synthetic sequences are not isolated from cellular chromatin based on altered reactivity to a probe of chromatin structure and, as such, do not necessarily and inevitably correspond to accessible regions, as required to show anticipation. In fact, the chance that an array of synthetic 10-mers would represent the same sequences corresponding to accessible regions is astronomically small – certainly not the “necessary and inevitable” standard required to establish inherent anticipation.

Turning to the Examiner’s assertion that the claimed arrays are not structurally distinguishable from Brennan’s arrays, Applicants note, as set forth in MPEP § 2113:

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<sup>1</sup> Applicants also note that it is axiomatic that claim terms are construed according to the ordinary and customary meaning the term would have to a person of ordinary skill in the art in question at the time of the invention. See, MPEP § 2111 and *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005). In the instant case, the skilled artisan at the time of filing would have no doubts as to what was meant by a sequence corresponding to an accessible region and, moreover, would know that synthetic 10-mers would not always be accessible regions. See, also Ref. A34 of the IDS filed December 8, 2005 as well as references in the attached IDS regarding the ordinary meaning of the term “accessible region of cellular chromatin.”

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

For the reasons noted above, in the instant case, the product (array of sequences corresponding to accessible regions) produced by the claimed process steps (isolating accessible region sequences based on altered reactivity to a probe of chromatin structure) is structurally distinguishable from Brennan's arrays because the claims arrays are all sequences corresponding to accessible regions while Brennan's are not. Simply put, isolation of sequences corresponding to accessible regions as claimed results in an array in which is structurally different than an array of synthetic 10-mers.

Therefore, because Brennan does not explicitly or inherently disclose all the elements of the claims and because the recited process steps impart structural limitations that distinguish the claims from the arrays of the cited reference, Brennan cannot anticipate any of the pending claims and withdrawal of the rejection is in order.


**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that all of the pending claims are in condition for allowance and request early notification to that effect.

Should the Examiner have any further questions, Applicants request that the undersigned be contacted at (650) 493-3400.

Respectfully submitted,

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